

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

GRISSELLE RAMOS, on behalf of herself and)	
all others similarly situated)	
	Civil Action No. 08cv2703
Plaintiff,)	
)
v.)	Judge Lefkow
)
PLAYTEX PRODUCTS, INC., RC2)	Magistrate Judge Schenkier
CORPORATION, LEARNING CURVE)	
BRANDS, INC., and MEDELA, INC.)	ORAL ARGUMENT REQUESTED
)
Defendants.)	
_____)	
DINA SCALIA, JENNIFER SUAREZ, and)	
MARISSA LOPEZ, on behalf of themselves)	Case No. 08cv2828
and all others similarly situated)	
)
Plaintiffs,)	Judge Lefkow
)
v.)	Magistrate Judge Schenkier
)
PLAYTEX PRODUCTS, INC., RC2)	ORAL ARGUMENT REQUESTED
CORPORATION, LEARNING CURVE)	
BRANDS, INC., and MEDELA, INC.,)	
)
Defendants.)	

**DEFENDANT MEDELA INC.'S BRIEF IN SUPPORT OF ITS MOTION
FOR ENTRY OF A CASE MANAGEMENT ORDER PURSUANT TO RULE 16(c)(12)**

Plaintiffs in these cases have alleged that their children have been exposed to lead from defendants' products. That very serious accusation, which underlies all of Plaintiffs' claims, is without any reasonable basis in fact. Plaintiffs were legally obligated, pursuant to Rule 11, to make a reasonable inquiry and possess a factual basis for their claims *prior* to filing their complaints. Fairness to Defendant Medela Inc. ("Medela"), and to the Court, requires that

Plaintiffs present such information before imposing on Medela the costly discovery and litigation burdens of a nationwide class action. Accordingly, Defendant Medela Inc. (“Medela”) respectfully requests entry of a case management order, pursuant to Rule 16(c)(12) of the Federal Rules of Civil Procedure, requiring Plaintiffs to present, prior to the exchange of initial disclosures and any other discovery, the factual information that constitutes the basis for their allegations and claims of lead exposure, including the following basic information: (1) the specific Medela product(s) at issue in this case; (2) evidence of actual exposure to lead (*i.e.*, human contact with lead in the product); and (3) the nature and extent of such exposure to lead.

BACKGROUND

Plaintiffs filed these putative nationwide class actions against Medela and three other defendants unrelated to Medela, asserting various claims premised on the allegation that “Plaintiffs’ children and the children of the [putative] Class have been significantly exposed to a known hazardous substance [lead]”, and that “[a]s a result of such exposure, the children are at an increased risk of being poisoned by lead.” (Ramos Compl. at ¶ 6; *see also id.* at ¶¶ 62, 73, 81, 86-87).¹ Despite such a serious allegation, Plaintiffs fail to set forth the most basic information about their claims:

- (1) the specific Medela product(s) at issue in this case;
- (2) evidence of actual exposure to lead (*i.e.*, human contact with lead in the product); and
- (3) the nature and extent of such exposure to lead.

Plaintiffs’ counsel recently informed counsel for Medela, in a May 20, 2008 meeting, that they did not conduct lead testing of any kind, and that they were unaware of any

¹ Plaintiff Grisselle Ramos filed this putative class action on May 9, 2008. Plaintiffs Dina Scalia, Jennifer Suarez, and Marissa Lopez filed a nearly-identical putative class action on May 15, 2008. By order of the Executive Committee of the Northern District of Illinois, dated June 11, 2008, the second case was re-assigned to this Court.

testing of Medela product indicating release of lead from the product. (See Declaration of Susan M. Benton, ¶¶ 2, 3B (attached as Ex. A)). Instead, Plaintiffs' counsel took their allegations from newspaper articles describing allegations made against the defendants by California's Center for Environmental Health ("CEH"). (*Id.* at ¶ 3C.) Significantly, CEH *withdrew* its allegations after reviewing Medela's test data demonstrating no lead exposure. (*Id.* at ¶ 4.) Moreover, Medela is not aware of any lead exposure, or claims of lead-related harm, from its products.

Plaintiffs have alleged only that they have a third party's data showing a purported level of lead "content" in unspecified Medela products. (Ramos Compl. at ¶¶ 4, 30-32.) Plaintiffs apparently seek to infer actual "exposure to lead" from alleged imbedded lead content in a product. But such an inference is invalid and improper because the lead content of a product does not equate to human exposure to lead as a result of use of the product. Lead exposure requires human contact with lead. According to the *Guidelines on Exposure Assessment* published by the United States Environmental Protection Agency, "exposure to a chemical is the contact of that chemical with the outer boundary [of the human body]." *Guidelines for Exposure Assessment*, 57 Fed. Reg. 22888, 22891 (May 29, 1992). For example, computer monitors contain substantial quantities of lead but an individual's use of a monitor does not equate to that person's contact with lead, *i.e.* lead exposure, because the lead within the monitor is inaccessible to the user. Without actual contact with the lead, there can be no harm from lead in a product. Therefore, before proceeding with this lawsuit, Plaintiffs should be required to present the factual bases for their allegations of actual exposure and consequent injury.

In cases such as this, federal and state courts often issue case management orders compelling plaintiffs to present their *prima facie* case before imposing unnecessary costs and

burdens on defendants in defending against claims that lack a reasonable basis in fact. Defendant Medela requests that the Court issue such an order here.

ARGUMENT

I. RULE 16 BROADLY EMPOWERS THIS COURT TO ENTER A CASE MANAGEMENT ORDER TO HANDLE LITIGATION EFFICIENTLY.

Rule 16 provides federal courts with substantial authority to fashion an efficient and cost-effective approach to managing and disposing of litigation. As the Seventh Circuit stated in *G. Heileman Brewing Co., Inc. v. Joseph Oat Corp.*, 871 F.2d 648, 652 (1989): “The wording of the rule and the accompanying commentary make plain that the entire thrust of the amendment to Rule 16 was to urge judges to make wider use of their powers and to manage actively their dockets from an early stage.” Similarly, the Advisory Committee Notes for this Rule state that “[i]ncreased judicial control during the pretrial process accelerates the processing and termination of cases.” Flanders, *Case Management and Court Management in United States District Courts*, 39 Federal Judicial Center (1977).

Subpart (c) of Rule 16 enumerates various actions available to the Court to accomplish these objectives. One provision authorizes the Court to take appropriate action with respect to:

... the need for adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions or unusual proof problems.

Fed. R. Civ. P. 16(c)(12).

Federal and state courts alike often have employed this Rule to require plaintiffs to come forward with basic facts to support their allegations before the case proceeds with discovery. *See, e.g., Acuna v. Brown and Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000). Such

orders, commonly referred to as “*Lone Pine*” orders,² screen out meritless claims at an early stage of the litigation and avoid unnecessarily protracted and wasteful litigation.

Consistent with the purposes of Rule 16, *Lone Pine* orders are tailored to fit the circumstances of each case. In many instances, a *Lone Pine* order has directed the plaintiffs to provide expert affidavits detailing key elements of the plaintiffs’ case, such as the existence, extent, and manner of the alleged exposure to a chemical substance, and the alleged causal connection between that exposure and the asserted injuries. *See e.g., Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598, 604 n.2 (5th Cir. 2006) (“The *Lone Pine* order issued in this case requires that individual plaintiffs each produce, depending on the type of injury alleged, either an affidavit from a qualified treating or other physician, or an affidavit from a qualified real estate appraiser or other real estate expert.”); *In re Mohawk Roba Co.*, 982 S.W.2d 494, 496 (Tex. Ct. App. 1998) (*Lone Pine* order required plaintiffs to provide medical evidence to support claim that defendants caused harm).

The *Acuna* case is instructive. In that case, the district court was presented with a large number of plaintiffs suing numerous defendants for injuries occurring over many years. The court issued pre-discovery *Lone Pine* orders requiring the plaintiffs to submit expert affidavits with specific information establishing, for each plaintiff, “the nature of his injuries, the circumstances under which he could have been exposed to harmful substances, and the basis for believing that the named defendants were responsible for his injuries.” *Acuna*, 200 F.3d at 338, 340. The Fifth Circuit held that it was within the district court’s “wide discretion” under Rule 16 “to take steps to manage the complex and potentially burdensome discovery that the cases would

² These orders are named after an opinion from the Superior Court of New Jersey, *Lore v. Lone Pine Corp.*, 1986 N.J. Super. LEXIS 1626 (N.J. Super. Law. Div. November 18, 1986). We cite *Lone Pine* not as precedent, but as an example that Federal courts routinely cite in endorsing these kinds of case management orders as a proper exercise of a District Court’s authority under Rule 16(c)(12). *See e.g., Acuna*, 200 F.3d at 340.

require" by "refusing to allow discovery to proceed without better definition of plaintiff's claims." *Id.* at 340-341.

Courts frequently use *Lone Pine* orders to require plaintiffs to detail the existence, manner, and extent of exposure. For example, in *Baker v. Chevron*, 2007 U.S. Dist LEXIS 6601 (S.D. Ohio, Jan. 30, 2007), the district court required plaintiffs to provide an affidavit from a qualified expert providing, among other things, "the alleged manner of exposure, and the date, duration, and dose of the exposure." In *Abuan v. General Electric Co.*, 3 F.3d 329, 331 (9th Cir. 1993), the Ninth Circuit affirmed summary judgments for defendants because, in response to a case management order, plaintiffs failed to "file and serve on defendants all medical and scientific opinions of experts, based on a reasonable degree of medical or scientific certainty and expressed in report form supporting each claimant's claim that he or she was exposed to a sufficient level of PCBs, PCBFs and/or dioxins as a result of the PITI Power Plant incident to require future medical monitoring of said claimant and that such exposure placed claimant at increased risk of future injury, illness or disease." *See also Bell v. Exxon Mobil Corp.*, No. 01-04-00171-CV, 2005 Tex. App. LEXIS 1680 at 3 (Tex. Ct. App. Mar. 3, 2005) (*Lone Pine* order required plaintiffs to submit expert affidavits detailing "the manner and duration of the exposure" and stating an opinion that "to a reasonable medical probability, the injury[s] sustained because of that exposure) (emphasis added); *Myer v. Creative Nail Design, Inc.*, 975 P.2d 1264, 1266, 1271 (Mont. 1999) (*Lone Pine* order requiring each plaintiff to provide a list of products used, the circumstances of exposure, and identification of each specific chemical which allegedly caused harm, and a physician's opinion of the causal connection between the exposure and the injury); and *In re Love Canal Actions*, 547 N.Y.S.2d 174, 179 (N.Y. Sup. Ct. 1989) (*Lone Pine* order requiring each plaintiff to provide evidence of exposure, injury and causation).

In sum, it is well-settled that this Court has the authority to enter a case management order, pursuant to Rule 16(c)(12), requiring Plaintiffs to present, prior to the exchange of initial disclosures and any other discovery, the factual information that constitutes the basis for their allegations and claims of lead exposure.

II. EXPOSURE, DOSE, AND A REASONABLE CONNECTION TO PLAINTIFFS' ASSERTED INJURIES ARE NECESSARY PREDICATES OF PLAINTIFFS' CLAIMS.

The instant cases are precisely the sort of case that would benefit from a *Lone Pine* order. These class actions, premised entirely on allegations of exposure to lead, present many of the same issues that courts have sought to address through the use of *Lone Pine* orders in cases cited above. Plaintiffs allege that their children have been exposed to lead, but the complaint offers no clue as to the particular products at issue; as to the nature, extent, or manner of exposure; or as to the causal connection between the exposure and the claimed injuries. *These are key foundational facts that Plaintiffs should present at the earliest possible stage of the litigation*, through entry of an appropriate case management order.

A. Factual support for exposure allegations.

Where the asserted tort involves alleged exposure to chemicals, “a plaintiff must establish that he or she came into contact with the chemicals produced by defendants.” *Donaldson v. Cent. Ill. Pub. Serv. Co.*, 199 Ill. 2d 63, 91 (2002) (citing *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 782 (10th Cir. 1999)). While *Donaldson* states that a plaintiff might not be required to quantify the exposure under Illinois law, *Mitchell* discusses the law in other jurisdictions that *do* require plaintiffs to quantify exposure.³ The Tenth Circuit in *Mitchell*

³ These other jurisdictions are important here because Plaintiffs have asserted a nationwide class action, and the putative class members' rights will be affected by the law of the jurisdictions that are relevant to them.

explained that actual exposure, and the level of that exposure, were essential aspects of a toxic tort claim:

It is well established that a plaintiff in a toxic tort case must prove that he or she was exposed to and injured by a harmful substance manufactured by the defendant. *Wright v. Willamette Industries, Inc.*, 91 F.3d 1105, 1106 (8th Cir. 1996); *Wintz By and Through Wintz v. Northrop Corp.*, 110 F.3d 508, 515 (7th Cir. 1997); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 199 (5th Cir. 1996). In order to carry this burden, a plaintiff must demonstrate “the levels of exposure that are hazardous to human beings generally as well as the plaintiff’s actual level of exposure to the defendant’s toxic substance before he or she may recover.” *Wright*, 91 F.3d at 1106. Although the district court, in this case, did not focus on Mitchell’s level of exposure to Defendant’s chemicals, our review of the record suggests that the information relied upon by Plaintiffs’ experts with respect to Mitchell’s level of exposure was “so sadly lacking as to be mere guesswork.” See *Allen*, 102 F.3d at 194. The record demonstrates that Plaintiffs attempted to establish Mitchell’s level of exposure in two ways. First, Plaintiffs attempted to establish Mitchell’s level of exposure through his own statements describing the number and length of visits he made to the “flammable room.” Second, Plaintiffs attempted to set the level of exposure through Steve Herron, an industrial hygienist, who after studying material safety data sheets and pictures showing some chemical spillage, opined that Mitchell’s exposure to Defendant’s products caused him to develop chronic myelogenous leukemia. These attempts fall short.

Mitchell, 165 F.3d at 781 (emphasis added). The Tenth Circuit also emphasized the need for valid expert testimony to establish the level of exposure:

We believe a plaintiff must prove level of the exposure using techniques subject to objective, independent validation in the scientific community. See *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (*en banc*). At a minimum, the expert testimony should include a description of the method used to arrive at the level of exposure and scientific data supporting the determination. The expert’s assurance that the methodology and supporting data is reliable will not suffice. *Id.* “Scientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff’s burden in a toxic tort case.” *Allen*, 102 F.3d at 199. Absent supporting scientific data, Mitchell’s estimates and Herron’s conclusions are little more

than guesswork. Guesses, even if educated, are insufficient to prove the level of exposure in a toxic tort case. *See Daubert*, 509 U.S. at 589, 113 S.Ct. at 2795 (unsupported speculation and subjective belief insufficient to meet Fed. R. Evid. 702's reliability requirement).

*Id.*⁴

Because actual exposure, and in many jurisdictions the levels of exposure, are necessary predicates of Plaintiffs' claims here, Plaintiffs should be required to present factual evidence to support their allegations of lead exposure from Medela's product(s).

B. Factual support for a "reasonable connection" between the asserted exposure and the claimed injuries/damages.

Causation is a core element in any tort case. As the Illinois Supreme Court explained in *Smith v. Eli Lilly and Co.*, 137 Ill. 2d 222, 232 (1990), "In a negligence action, this causation-in-fact requirement entails a 'reasonable connection' between the act or omission of the defendant and the damages. *Cf., Lewis v. Lead Industries Ass'n*, 342 Ill. App. 3d 95, 103 (2003). A "reasonable connection" is particularly important as a threshold matter in a case like this, in which the chemical at issue is truly ubiquitous.

All individuals are exposed to lead, to varying degrees, from a myriad of sources, from ceramic ware pottery or crystal, to drinking water (as a result of lead pipes or plumbing material), to soil that can contain lead from innumerable sources. Plaintiffs cannot carry their burden in this case merely by showing that their children were exposed to lead from Medela's product(s). Plaintiffs also need to establish a "reasonable connection" between any such exposure and the asserted injury/damages. That, in turn, would require an assessment of exposure (and exposure levels) from all other sources -- exposures that Medela respectfully

⁴ See also *Burns v. Universal Crop Protection Alliance, et al.*, 2007 U.S. Dist. LEXIS 71716 (Sept. 25, 2007) (in course of issuing *Lone Pine* order, Court stated that plaintiffs must introduce sufficient evidence that exposure to a particular defendants' product was a substantial factor in producing the asserted injury).

submits would dwarf any exposures that Plaintiffs may attribute to Medela's product(s). Accordingly, Plaintiffs should be required to provide an expert affidavit explaining this "reasonable connection."

C. Medela's motion does not seek a determination of the merits of Plaintiffs' claims.

Plaintiffs may assert that Medela's motion for entry of a case management order is a premature request to determine the merits of Plaintiffs' claims, but such an assertion would be very wide of the mark. Plaintiffs were legally obligated, pursuant to Rule 11, to make a reasonable inquiry and possess a factual basis for their claims *prior* to filing their complaints. *See* Fed. R. Civ. P. 11(b)(3); *Acuna*, 200 F.3d at 340 (required production of that information which plaintiff should have had before filing their claims pursuant to Rule 11(b)(3)). Judge Easterbrook explained just last month that a party must conduct a reasonable inquiry *before* advocating a position, and that advancing a position which never had evidentiary support violates Rule 11. *United Stars Industries, Inc. v. Plastech Engineered Products, Inc.* 525 F.3d 605, 610 (7th Cir. 2008); *see also Jimenez v. Madison Area Technical College*, 321 F.3d 652, 656 (7th Cir. 2003) (stating that Rule 11 requires that the allegations and other factual contentions in a pleading have evidentiary support). Thus, Plaintiffs must have *some* information regarding their exposure allegations, the circumstances under which they could have been exposed to lead, and the basis for believing that the defendants were responsible for their injuries. *See Leuallen v. Burrough of Paulsboro*, 180 F. Supp.2d 615, 617 (D.N.J. 2002) (Rule 11 requires attorneys, before filing a complaint, to make a reasonable inquiry into the existing facts and law that form the basis of the complaint's claims).

As Plaintiffs were required to develop the information which is the subject of this motion before filing their complaints, it follows that Plaintiffs need no discovery to respond to

this motion. Plaintiffs should be required to provide that information now so that further orders can be issued to structure this case in the most logical and cost-effective way possible.

CONCLUSION

For the foregoing reasons, Medela Inc. respectfully requests that the Court enter a case management order, pursuant to Rule 16(c)(2), that requires Plaintiffs to come forward with basic evidence, as described above, to support their allegations prior to the exchange of initial disclosures or other discovery. A proposed order is attached as Exhibit B, and Medela respectfully requests the opportunity to present oral argument in support of this motion.

Dated: June 23, 2008

Respectfully submitted,

MEDELA INC.

By: /s/ Susan M. Benton
One of Its Attorneys

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of June 2008, I caused a copy of the foregoing document, DEFENDANT MEDELA INC.'S BRIEF IN SUPPORT OF ITS MOTION FOR ENTRY OF A CASE MANAGEMENT ORDER PURSUANT TO RULE 16(c)(12), to be filed electronically. Notice of this filing will be sent to the following counsel by operation of the Court's ECF system. Parties may access this filing through the Court's system.

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/s/ Kevin A. Banasik

Exhibit

A

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

GRISSELLE RAMOS, on behalf of herself and)	
all others similarly situated)	
	Civil Action No. 08CV2703
Plaintiff,)	
)
v.)	Judge Lefkow
)
PLAYTEX PRODUCTS, INC., RC2)	Magistrate Judge Schenkier
CORPORATION, LEARNING CURVE)	
BRANDS, INC., and MEDELA, INC.)	
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Defendants.)	
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DINA SCALIA, JENNIFER SUAREZ, and))
MARISSA LOPEZ, on behalf of themselves)	Case No. 08cv2828
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)
Plaintiffs,)	Judge Lefkow
)
v.)	Magistrate Judge Schenkier
)
PLAYTEX PRODUCTS, INC., RC2))
CORPORATION, LEARNING CURVE)	
BRANDS, INC., and MEDELA, INC.,)	
)
Defendants.)	

**DECLARATION OF SUSAN M. BENTON IN SUPPORT OF MEDELA INC.'S MOTION
FOR ENTRY OF A CASE MANAGEMENT ORDER PURSUANT TO RULE 16(c)(12)**

I, Susan M. Benton, declare under penalty of perjury, in accordance with 28 U.S.C. § 1746, as follows:

1. I am a partner in the law firm Winston & Strawn LLP, and I am one of the attorneys representing Medela Inc. ("Medela"), which is one of the defendants in the above-captioned cases.

2. Carr Lane Quackenbush, President of Medela, and I met with plaintiffs' counsel, Mary Jane Fait and John Tangren, of the law firm Wolf Haldenstein Adler Freeman & Herz LLC, on May 20, 2008 at the offices of Winston & Strawn to discuss the allegations of the Complaint.

3. At the May 20 meeting, Mary Jane Fait stated that:

- A. Plaintiffs' counsel is not sure which Medela products are at issue in the Complaint.
- B. Prior to filing the lawsuit, and as of May 20, Plaintiffs' counsel had conducted no testing of any kind on Medela products, were not aware of any lead exposure testing on Medela products, and were not aware of any testing of a Medela product indicating release of lead from the product.
- C. Plaintiffs' counsel took the lead exposure allegations of the Complaint from newspaper articles referencing allegations made against the defendants by the California Center for Environmental Health ("CEH") in a Notice of Violation dated January 31, 2008.

4. After CEH reviewed Medela's test data, which demonstrated no lead exposure, on or about May 19, 2008, CEH informed Medela that it had decided not to pursue its Notice of Violation against Medela.

Executed this 23rd day of June, 2008, in Chicago, Illinois

/s/ Susan M. Benton
Susan M. Benton

Exhibit

B

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

GRISSELLE RAMOS, on behalf of herself and)	
all others similarly situated)	
	Civil Action No. 08cv2703
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DINA SCALIA, JENNIFER SUAREZ, and)	Case No. 08cv2828
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and all others similarly situated)	
	Judge Lefkow
Plaintiffs,)	
) Magistrate Judge Schenkier
v.)	
)
PLAYTEX PRODUCTS, INC., RC2)	
CORPORATION, LEARNING CURVE)	
BRANDS, INC., and MEDELA, INC.,)	
)
Defendants.)	
)

**[PROPOSED]
CASE MANAGEMENT ORDER #1**

Defendant Medela Inc. (“Medela”) has moved this Court for entry of a case management order pursuant to Federal Rule of Civil Procedure 16(c)(12). The Court, having reviewed the parties’ respective papers and having considered the parties’ arguments on this motion, and the Court being fully advised in the premises, the Court finds that there is good cause to issue this Case Management Order #1, and

IT IS HEREBY ORDERED that Medela's motion for entry of a case management order is granted as follows:

1. Within 45 days from entry of this Case Management Order #1, Plaintiffs shall provide affidavits from fact or expert witnesses that provide the following information:
 - A. The specific Medela product or products at issue in this case by name and model number;
 - B. Evidence of actual exposure to lead (*i.e.*, human contact with lead in the product); and
 - C. The nature and extent of such exposure to lead, including but not limited to the dose/level and duration of such exposure from Medela's product(s).
2. If Plaintiffs rely on expert opinion(s) to support the allegation that they were exposed to lead from Medela's product(s), Plaintiffs shall identify each expert relied upon along with his or her qualifications to provide the opinion(s), and each expert's affidavits shall state the preliminary facts, data, and other grounds relied on by him or her for each such opinion.
3. All discovery in this action, including but not limited to the exchange of initial disclosures pursuant to Rule 26(a), shall be stayed until further order of the Court.
4. A Rule 16 pre-trial scheduling conference, pursuant to Rule 16, is set for _____ 2008, at _____ (a.m. / p.m.)

Dated: _____

The Honorable Joan Lefkow
United States District court Judge